



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,282	05/19/2004	Maxine G. Moldenhauer	1032-US2	6646
35159	7590	12/27/2005	EXAMINER	
TARO PHARMACEUTICALS 5 SKYLINE DRIVE HAWTHORNE, NY 10532			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 12/27/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/849,282

Applicant(s)

MOLDENHAUER, MAXINE G.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed September 30, 2005 have been entered. Claims 1-5 are pending. The outstanding rejection under 35 USC 112, first paragraph is withdrawn in view of the amendments filed September 30, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,696,105 ('105).

'105 teaches topical cream composition comprising 0.01 to 0.25% or 0.05 to 0.15% of mometasone.furoate, Hexylene glycol, 1-5% of purified water, 2 to 10% of white wax, 4-12% of lipophilic surfactant having HLB value below 5 and 0.7 to 4% of a hydrophilic surfactant having HLB value above 11 such as cetareth-20, 0.2-2% of

Art Unit: 1617

titanium Dioxide, 5-20% of aluminum starch octenylsuccinate, 40-70% of White Petrolatum, and sufficient phosphoric acid to adjust the pH (See col. 4, lines 15-30). '105 also teaches a topical lotion formulated using a hydro-alcoholic base comprising 10-50% of propylene glycol (See col. 3, lines 32-46; col. 5-7, Examples 1-5).

'105 does not expressly teach the viscosity of the composition as about 400,000 to about 900,000 centipoise. '105 does not expressly teach the topical composition having propylene glycol instead of hexylene glycol.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate propylene glycol for hexylene glycol in the mometasone topical composition. It would have been obvious to one of ordinary skill in the art at the time of invention to adjust the viscosity of the mometasone topical composition.

One of ordinary skill in the art would have been motivated to incorporate propylene glycol for hexylene glycol in the mometasone topical composition. Propylene glycol is known to be useful in formulating a mometasone topical composition. Since propylene glycol is a well-known hydro-alcoholic base for topical composition, one of ordinary skill in the art would see the substitution of propylene glycol for hexylene glycol as selection among the obvious alternatives. Furthermore, the optimization of the effect parameter (e.g., viscosity for topical composition) would be obvious as being within the purview of skilled artisan.

Response to Arguments

Applicant's arguments filed September 30, 2005 averring the failure of the cited prior arts to teach polyethylene glycol as suitable in the topical cream formulation have

Art Unit: 1617

been considered, but are not found persuasive. '105 clearly teaches polyethylene glycol as one of the ingredients in mometasone topical formulation (See col. 3, lines 32-46). '105 even teaches the specific amount range for polyethylene glycol. Therefore, the claims are considered properly rejected under 35 USC 103(a).

Applicant's arguments with regard to US patent 4,808,610 are considered moot since the outstanding rejection under 35 USC 103 is not based on US 4,808,610.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


San-ming Hui
Primary Examiner
Art Unit 1617